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Entire Nexium MDL Closed After Expert Excluded; Defense Awarded Costs

LOS ANGELES — (Mealey's) The California federal judge overseeing the Nexium bone injury multidistrict litigation on Oct. 8 entered judgment in favor of manufacturer defendant AstraZeneca Pharmaceuticals LP and related entities and against all plaintiffs and ordered that the defendants "shall recover their costs of suit pursuant to a bill of costs" under statutory and federal court rules (In Re: Nexium [Esomeprazole] Products Liability Litigation, MDL Docket No. 2404, No. 12-ml-2404, C.D. Calif.).

(Judgment available. Document #28-141016-005R.)

The judgment by Judge Dale S. Fischer of the U.S. District Court for the Central District of California ends 22 cases that were pending in the MDL as of Sept. 15, according to statistics kept by the Judicial Panel on Multidistrict Litigation. When the MDL was created in 2012, the panel indicated that the cases represented more than 1,000 plaintiffs.

Judge Fischer's Oct. 8 order followed her Sept. 30 and Oct. 1 orders in which she granted, on briefings alone, a defense motion to exclude plaintiffs' general causation expert B. Sonny Bal, M.D., and granted summary judgment.

Epidemiological Qualification Lacking

Bal offered testimony that Nexium is generally capable of causing osteoporosis, osteopenia and osteoporotic fractures (collectively OP) even if the drug may not be the specific cause of OP in any plaintiff, according to Judge Fischer's opinion. She said that most of Bal's testimony is based on epidemiology, not orthopedics, the latter beingBal'smedical specialty.

"While a physician should have general skills to interpret epidemiological studies published in medical literature, it is certainly not clear that a non-epidemiologist has the necessary qualifications to conclude causation from a review of epidemiological studies that do not, themselves, reach such a conclusion," the judge wrote. "However, the Court need not definitively decide whether Bal is qualified to offer his opinions because the Court finds that those opinions are not reliable under the Daubert [Daubert v. Merrell Dow Pharmaceuticals, Inc.(509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 [1993])] [enhanced opinion available to lexis.com subscribers] standards."

"The main question, as the Court sees it, is whether Bal's testimony is reliable," the judge continued. "In this case, that means asking whether he used accepted methodology to come to his conclusion that the observed association of PPIs' [proton pump inhibitors] with OP indicates that Nexium causes OP. The Court finds that he did not."

"It is important to preface the discussion by noting that, even on his own terms, Bal does not provide a particularly strong opinion in favor of causation," the judge wrote. "His expert opinion does not directly state that he believes that Nexium causes OP."

Bradford Hill Criteria

"The parties agree that, as a matter of accepted epidemiological practice, mere association (or correlation) between Nexium use and OP is not sufficient to infer that Nexium causes OP," Judge Fischer said. "The parties also broadly agree that the factors laid out in a well-known epidemiology paper by Austin Bradford Hill should be analyzed to determine whether causation can be inferred from a correlation between Nexium and OP. Bal does not seriously evaluate any of these factors."

Comparing Bal's testimony against the Bradford Hill criteria, Judge Fischer said she "finds that Bal's report and expected testimony does not comport with epidemiological methodology as agreed to by the parties. Because of this, it is not reliable under the Daubert standard."

The judge noted that she offered the parties the opportunity to request a Daubert hearing but there was no response.

Summary Judgment Order

In her Oct. 1 order, Judge Fischer said, "There is no dispute that Plaintiffs cannot establish their prima facie cases without that evidence. Therefore, Defendants' motion for summary judgment is GRANTED."

The judge ordered AstraZeneca to lodge a proposed judgment by Oct. 9. In its Oct. 3 proposed judgment, AstraZeneca proposed that the judge order that "Defendants are allowed their recoverable costs."

On Oct. 8, the plaintiffs objected to including recoverable costs because the court's orders did not include a finding of awardable costs. They said Local Rule 54-3 provides a procedure and regulation and limitations on recoverable costs and that procedure should be followed by the defendants.

(**Plaintiffs' objections to proposed judgment available. Document #28-141016-008X.**)

Basis For Cost Recovery

Later that day, Judge Fischer entered her order and said the defendants shall recover their costs through a bill of costs filed in accordance with 28 U.S. Code Section 1920 and Federal Rule of Civil Procedure 54(d)(1).

Section 1920 allows a court to tax costs for court costs and fees. Rule 54(d)(1) allows for the awarding of costs other than attorney fees.

Nexium is an oral proton pump inhibitor drug used to treat heartburn, acid reflux and esophageal inflammation. It had been a prescription drug and became available overthecounter this year.

Only 55 Cases At Peak

The MDL was created in 2012. The highest number of cases was 55.

The plaintiffs are represented by Thomas V. Girardi and Keith D. Griffin of Girardi Keese in Los Angeles.

AstraZeneca is represented by Amy K. Fisher, Bonnie L. Gallivan, Katherine A. Winchester and Audra J. Ferguson-Allen of Ice Miller in Indianapolis.

[Editor's Note: Lexis subscribers may download the documents using the link above. The documents are also available at www.mealeysonline.com or by calling the Customer Support Department at 1-800-833-9844.]

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